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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,667	BARNIKOL ET AL.	
	Examiner	Art Unit	
	Abigail Fisher	4173	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5 Sheets*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-23 are pending.

Information Disclosure Statement

The inclusion of a copy of an International Search Report in the IDS has not been considered because these are non-published documents and can not be properly cited on a 1449 due to lack of a date of publication.

Election/Restrictions

The requirement of restriction set forth in the office action dated August 9 2007 has been withdrawn.

Examiner Notes

Claims 7-11 and 13 as written do not contain appropriate Markush language. The claim as written includes the phrase "selected from among". This phase implies open claim language however a Markush group is a group that is by nature closed. Examiner suggests rewording the claim to include the appropriate language.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the octane diol referred to in the specification is 1,2-octane diol however as claimed it is 1,6-octane diol.

Claim Objections

Claim 11 is objected to because of the following informalities: the examiner believes there is a type. The claim as written states, "wherein it dermatologically effective agents...". It is believed that the word contains is missing. Appropriate correction is required.

Claim 20 is objected to because of the following informalities: the examiner believes there is a typo. The claim as written states, "claim 1, as or for...". It is believed as and or should be eliminated in the sentence. Appropriate correction is required.

Claims 18 and 22 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. For claim 18: the claim is confusing. However the examiner believes that an interpretation of the claim is that the preparation represents a composition of claim 1. This does not further limit claim 1. The claim then goes on to be directed to a mixture thereof where an aqueous phase is included. This aqueous phase is broader than claim 1. The preparation then contains 1 to 50 wt % of an oil phase, which is broader, then claim 1. For claim 22: the claim recites wherein a preparation is used. However this claim depends from 21, which depends from 20, which already recites the use of a preparation. Therefore the claim is not further limiting.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 20-23 provides for the use of a micro-emulsion, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 20-23 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 7 and 9 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time

the application was filed, had possession of the claimed invention.

The specification discloses chemicals, such as lecithin, phosphatidyl choline, and polysaccharide, which meet the written description and enablement provisions of 35 USC 112, first paragraph. However, claims 4,7 and 9 are directed to encompass derivatives, which only correspond in some undefined way to the specifically instantly disclosed chemicals. None of these derivatives meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed derivatives, analogs, etc., regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("

> [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only the above chemically structurally defined chemicals, but not the full breadth of the claim(s) meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115.)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-23 are rejected under 35 U.S.C. 112, second paragraph, because while the claims provide for the "use" of a micro-emulsion, the claims do not set forth any steps involved in the method/process, and thus it is unclear what method/process they are intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 7 recites the limitation "the lecithin, phosphatidyl choline or derivative thereof" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 23 recites the limitation "the emulsion" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 9, 11-14, 19-21, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Owen et al. (US Patent No. 5646109, found on PTO Form 1449).

Applicant Claims

Applicant claims a water-in-oil micro-emulsion that is free from cross-linking agents and comprises a liquid oil phase, a mixture of one or more water-in-oil and one or more oil-in-water surfactants, one or more emulsifiers, one or more monovalent or bivalent alcohols, and an aqueous phase. The micro-emulsion has a particle size of 20 to 400 nm. The emulsion can **optionally** be converted to a secondary water-in-oil micro-emulsion or an oil-in-water micro-emulsion. Therefore claim 1 can be interpreted two different ways. Claim 1 can be of a composition that is just a water-in-oil micro-emulsion **or** it is a composition that is a water-in-oil (W/O) micro-emulsion that is converted to a secondary water-in-oil micro-emulsion or an oil-in-water (O/W) micro-emulsion by the means of adding an aqueous phase.

The micro-emulsion also contains one or more active substances that are soluble in water or soluble in fat/oil. The micro-emulsion can also contain a mixture of both water-soluble and fat/oil soluble substances. The micro-emulsion also comprises additives. The emulsifiers of the micro-emulsion include one or more lecithins, phosphatidyl cholines or mixtures. The surfactants of the emulsion are non-ionic and those that are W/O surfactants have an HLB value of 3 to 7 and those that are O/W surfactants have an HLB of 9 to 18.

Claim 7 was previously rejected under 112, second paragraph because it lacks antecedent basis. The examiner believes its dependency was a typo and actually depends from claim 4 not claim 1. Therefore the rejection of claim 7 under 35 USC 103 is based on the assumption that claim 7 actually depends from claim 4.

The water-soluble active substances that are suitable include: amino acids, peptides, protein hydrolysates, proteins, saccharides, oligosaccharides, polysaccharides, hormones and substances similar to hormones, antioxidants, vitamins and pro-vitamins, AHA acids, NMF, oxidants, plant extracts, flavonoids, and plant polyphenols or mixtures thereof.

The micro-emulsion additionally contains dermatologically effective agents which include: hormones, antimycotics, scar treatment agents, tanning agents, tars, keratinolytics, keratinoplastics, photocumarins, acelainic acid or mixtures thereof.

The additives in the micro-emulsion include: electrolytes, oxidants, chelating substances, diffusion reinforcing agents, penetration promoting agents, moisturizers or mixtures thereof. The specification indicates that electrolytes include those based on organic anions like acetates (page 38 of the specification).

The micro-emulsion can also contain hemoglobin or myoglobin as well as antioxidants, glutathione, super-oxide dismutase, melatonin, flavonoids, amino acids or mixtures thereof.

Applicant additional claims a method for producing a micro-emulsion where the oil phase and any fat-soluble active substances, the surfactant (s), the emulsifier (s), the

alcohol (s), additives if applicable, an aqueous phase, and any water-soluble active substance(s) are mixed at a temperature from 10 to 30 °C. The primary water-in-oil is obtained and is converted to a secondary water-in-oil micro-emulsion or a secondary oil-in-water micro-emulsion with an aqueous phase.

Applicant claims uses of the micro-emulsions. Claims 20 and 21 are interpreted as being method of treating skin by topically applying the micro-emulsion as claimed above. The skin has been irritated or damaged or has degeneration due to allergy, bacteria, immunology, or external influences. While claim 23 lacks antecedent basis for the words "the emulsion". The examiner believes that this is typo and should read "the micro-emulsion". Claim 23 is interpreted, as being a product claim where in the micro-emulsion is a liquid and is sprayed on or is applied as a gel.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Owen et al. is directed to water-in-oil micro-emulsion. Disclosed that the water-in-oil micro-emulsion system is formulated that upon addition of water an oil-in-water micro-emulsion is formed (column 3, lines 56-59). Additionally disclosed that the water-in-oil micro-emulsion that is directly administered to the body of animals and the body fluids themselves covert the water-in-oil micro-emulsion to an oil-in-water emulsion (column 3, lines 34-40). The particle size of these micro-emulsions is generally less than about 0.1 microns (100 nm) (column 1, line 25). Owen et al. does not specify using cross-linking agents. Additionally the term cross-linking does not appear any where within the patent.

The micro-emulsion comprises an aqueous phase, a pharmaceutically acceptable oil, a surfactant or mixture of surfactants, a water-soluble biologically active material or combination of materials (column 4, lines 49-55). There may be other adjuvants included as well in the amount from 0 to 20% by volume (column 5, lines 62-67).

The water content of the water-in-oil micro-emulsion is up to as high as 60 volume percent (column 5, lines 20-23). The water component of the aqueous phase can be partially or fully replaced by the incorporation of another poly biologically compatible solvent such as polyhydrolic alcohols (column 5, lines 43-46). Therefore the total volume percent of water can be completely replaced by alcohol or contain no alcohol.

The oil may be liquid at room temperature (column 6, lines 6-7). The micro-emulsion can contain from about 30 to 99 volume percent of an oil phase (claim 12). The surfactant content ranges from 5 to 75 volume percent (column 5, line 29-31). Disclosed is that a mixture of surfactants is preferred when the water-in-oil micro-emulsion has an aqueous phase of greater than 20% by volume (column 6, lines 65-67). This mixture includes a high HLB surfactant or a mixture of high HLB surfactants. Sometimes it is preferred to have at least one surfactant with a high HLB and one surfactant with a low HLB resulting in an average HLB value from 7 to 14. High HLB surfactants have an HLB greater than 9 while low HLB have a value below 5 (column 7, lines 1-10). Non-ionic surfactants are suitable (column 7, lines 29-54). Example 4

includes Capmul MCM that is a water-in-oil surfactant with an HLB of 5 and Cremophor EL that is an oil-in-water surfactant with an HLB of 13.5 in a ratio of about 1:10.

While Owen et al. does not use the terminology emulsifier. It is well known in the art that an emulsifier is also known as a surfactant. Disclosed as suitable surfactants include lecithin (column 7, line 26). One preferred system includes liquid lecithin from central soya, which is a soybean lecithin, in an amount from about 1-2.5% w/w. This example also includes other surfactants like polyoxyethylene glycerol triricinoleate (column 14, lines 42-52).

The water-soluble active material that may be incorporated include: proteins, peptides, and other pharmaceutically active compounds (column 7, lines –59-62). The active material can comprise from 10^{-9} to 100 weight/volume % of the aqueous phase (column 5, line 14). Other material that is listed as suitable includes hemoglobin (column 8, line 5) and dismutases (column 8, line 35).

One preferred water-in-oil micro-emulsion includes as an active agent calcitonin, which is a generic peptide hormone (column 2 lines 53-54 and column 14, line 49). This example includes 100 mM acetate buffer, which can also be viewed as an electrolyte (column 14, line 49).

Example 1 discloses a method of producing the micro-emulsion. The components (oil phase, water phase, and surfactants) were mixed at 25 °C for about 3 minutes to provide a clear stable water-in-oil micro-emulsion. In example 2 water was then added to this micro-emulsion to convert the micro-emulsion to an oil-in-water emulsion.

Owen et al. discloses that the micro-emulsion can be used topically as well (column 15). It is ideally suited for wound care (column 15, line 14). The topical micro-emulsion is preferably presented in the form of a solid, salve or gel (column 15, lines 38-39).

Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)

Owen et al. does not specify a particular amount of alcohol that is suitable.

Owen et al. does not specify a particular ratio of surfactants in the range of 1:4 to 1:1.2.

Owen et al. does not specify that the water-soluble active material is hemoglobin or dismutase or a combination of the two.

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to vary the amount of alcohol of the invention depending on the other water-soluble agents added. One would have been motivated to do this because it is known based on the disclosure of Owen et al. that alcohols are acceptable as well as the fact that sometimes organic water-miscible solvents are needed to help dissolve the other water-soluble agents that may be added.

It would have been obvious to one of ordinary skill in the art to modify the ratio of surfactants in order to determine the optimal ratio of surfactants. It would have been obvious to one of ordinary skill in the art at the time of the invention to engage in route experimentation to determine optimal or workable ranges that produce excepted results.

Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. **In re Aller, 220 F. 2d 454, 105 USPQ 233 (CCPA 1955).**

It would have been obvious to one of ordinary skill in the art to use hemoglobin and/or dismutase as the water-soluble active material. One of ordinary skill in the art would have been motivated to do this because Owen et al. discloses them as a suitable water-soluble active material as well as combinations of biologically-active material is acceptable. A person of ordinary skill has a good reason to pursue the known options within their technical grasp, for example those disclosed by Owen et al. as being suitable. Thereby resulting in the practice of the instant application with a reasonable expectation of success.

The applicant has disclosed that the conversion of the water-in-oil micro-emulsion is converted to a secondary water-in-oil or oil-in-water micro-emulsion. The process as disclosed is that the primary micro-emulsion is mixed with one part aqueous solution resulting in a clear opaque micro-emulsion. This appears to be the same process that Owen et al. uses to arrive at their secondary oil-in-water emulsion. There does not appear to be any different process steps established by applicant that would differentiate the secondary emulsion formed by Owen et al. and that of the applicant.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Owen et al. in view of Chen et al. (US Patent No. 6267985).

Applicant Claims

Applicant claims a water-in-oil micro-emulsion as claimed above where in the alcohol is selected from ethanol, isopropanol, butanol, 1,6-octane diol, or 1,2-hexane diol.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Owen et al. are discussed above. Specifically Owen et al. teaches that the water component of the aqueous phase can be partially or fully replaced by the incorporation of another poly biologically compatible solvent such as polyhydrolic alcohols, like propylene glycol (column 5, lines 43-46).

Chen et al. is directed to pharmaceutical compositions for improved delivery of therapeutic agents (abstract). Chen et al. discloses that compounds that are suitable to be used in pharmaceutical compositions that can aid or enhance the solubility of therapeutic agents include alcohols and polyols such as ethanol, isopropanol, butanol, and propylene glycol (columns 33-34, lines 63-67 and 1-2).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Owen et al. does not specify using ethanol, isopropanol or butanol as alcohols that are suitable in the micro-emulsion.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to modify the alcohols that are used in the micro-emulsion. One of ordinary skill would have been motivated to do this in order to better solublize the therapeutic agent present in the invention. It would have been obvious to one of ordinary skill in the art at the time of the invention to engage in route experimentation to determine optimal or workable ranges that produce excepted results.

Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. **In re Aller, 220 F. 2d 454, 105 USPQ 233 (CCPA 1955).**

Claims 10 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Owen et al. in view of Nagahama et al. (US Patent No. 6303662).

Applicant Claims

The fat/oil soluble active substances that are suitable include: antioxidants, vitamins and pro-vitamins, unsaturated fatty acids, ceramides, ether oils or mixtures thereof.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Owen et al. are discussed above. Specifically Owen et al. discloses that oil-soluble drugs can also be included (column 5, lines 62-63). The amount that can be added is from 0 to 20% by volume (column 5, line 66).

Nagahama et al. discloses micro-emulsions comprising highly polar and fat-soluble oil drugs (abstract). Examples of highly polar and fat-soluble dugs include fat-

soluble vitamins such as riboflavin (column 3, lines 26-28). Riboflavin is especially preferred because of the stability of the drug (column 3, lines 60-61).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Owen et al. does not specify oil-soluble drugs that can be included in the micro-emulsion.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would of been obvious to one of ordinary skill in the modify the invention of Owen et al. and include Riboflavin as the oil-soluble drug. One would have been motivated to do this because it is disclosed as a suitable oil-soluble drug to be used in micro-emulsions and it has good stability and therefore there is a reasonable expectation that it will not adversely affect the other material in the micro-emulsion. Thereby arriving at the instant application with a reasonable expectation of success.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Owen et al. in view of Nagahama et al. (US Patent No. 6140375).

Applicant Claims

Applicant claims that the water-in-oil micro-emulsion further contains glucose.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Owen et al. are disclosed above. Specifically Owen et al. discloses that flavors can be included in the micro-emulsion.

Nagahama et al. discloses a micro-emulsion (abstract). This micro-emulsion includes sweetening agents like glucose (column 4, lines 9-10).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Owen et al. does not specify the types of flavors that can be added.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to include glucose in the invention of Owen et al. One of ordinary skill would have been motivated to do so because if the micro-emulsions are going to be administered orally it would be advantageous to have a sweetener added to minimize the bitter taste that can accompany orally administered drugs. Thereby arriving at the instant application with a reasonable expectation of success.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Owen et al. in view of Gehlsen (US PUGPUB No. 2001/0018059) and Mooney et al. (US Patent No. 5814031) and Martin (US Patent No. 5674912).

Applicant Claims

Applicant claims a water-in-oil micro-emulsion as recited above wherein it contains plant extracts in an amount of 0.1 wt. % to 5 wt. %, 0.1 wt. % to 5 wt. % ether oils, 0.1 wt. % to 10 wt. % AHA acids, 0.01 to 0.3 wt. % hormones or substances similar

to hormones, 0.1 to 5 wt. % essential fatty acids, ceramides, or mixtures thereof.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Owen et al. are discussed above. Specifically one preferred water-in-oil micro-emulsion includes as an active agent calcitonin, which is a generic peptide hormone (column 2 lines 53-54 and column 14, line 49). The active material can comprise from 10^{-9} to 100 weight/volume % of the aqueous phase (column 5, line 14). Owen et al. discloses that the micro-emulsion can be used topically as well (column 15). It is ideally suited for wound care (column 15, line 14). The topical micro-emulsion is preferably presented in the form of a solid, salve or gel (column 15, lines 38-39).

Gehlsen discloses compositions for treating cell damage in relation to a variety of skin disorders (abstract). Examples include treatment of thermal burns (example 15) and chemical burns (example 16). Compounds disclosed that can reduce skin irritation include aloe vera and chamomile (paragraph 0035).

Mooney et al. discloses compositions that can be applied directly to a wound (abstract). Disclosed as skin care agents and therapeutics that can be added include alpha hydroxyl acid (column 5, lines 51-55).

Martin discloses therapeutic sunscreen-wound healing compositions (abstract). Disclosed is that sometimes it is advantageous to include anti-inflammatory agents. These anti-inflammatory agents include evening primrose oil (column 50, lines 9-15).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Owen et al. does not disclose using other wound care agents in the micro-emulsion.

Finding of Prima Facie Obviousness Rational and Motivation

It would have been obvious to one of ordinary skill in the art to add other known wound care agents to the invention of Owen et al. One of ordinary skill would have been motivated to do so because Owen et al. disclosed that the micro-emulsions can be used for wound care therefore the addition of known compounds that are used for wound care would have at least an additive effect.

It would have been obvious to one of ordinary skill in the art to modify the amounts of wound care agents added in order to optimize the formulation of a wound care topical formulation. It would have been obvious to one of ordinary skill in the art at the time of the invention to engage in route experimentation to determine optimal or workable ranges that produce excepted results.

Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. **In re Aller, 220 F. 2d 454, 105 USPQ 233 (CCPA 1955).**

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pezzuto et al. (US Patent No. 6414037).

Applicant Claims

The claims also include a method of treating skin that has changed due to age by topical administration of the micro-emulsion as described above.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Pezzuto et al. discloses a method for preventing or treating skin conditions such as those that may be associated with natural aging (abstract). One form of the pharmaceutical formulation includes micro-emulsions. For the preparation of these micro-emulsions, surfactant (emulsifier), co-surfactant (co-emulsifier), an oil phase and a water phase are necessary (column 8, lines 53-67 and example 2). The example specifies that water is included in an amount of 0.3 wt. %. Also disclosed is that lower alkanols such as ethanol can be included to facilitate the passage of therapeutic levels of active agents through a reasonably sized area of unbroken skin (column 9, lines 45-49).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Pezzuto et al. does not specify a particular ratio of surfactant to co-surfactant.

Pezzuto et al. does not specify using alcohol in the micro-emulsion.

Pezzuto et al. does not specify the particular amount of water to be included but exemplifies a small percentage.

Finding of Prima Facie Obviousness Rational and Motivation

It would have been obvious to one of ordinary skill in the art to vary the amount of alcohol in the invention depending on the therapeutic agent included. One would have

been motivated to do this because it is known based on the disclosure of Pezzuto et al. that alcohols are acceptable and can be included to help facilitate the passage of therapeutic levels of active agents.

It would have been obvious to one of ordinary skill in the art to modify the ratio of surfactants as well as the amount of water in order to determine the optimal ratio of surfactants and amount of water. It would have been obvious to one of ordinary skill in the art at the time of the invention to engage in route experimentation to determine optimal or workable ranges that produce excepted results.

Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. **In re Aller, 220 F. 2d 454, 105 USPQ 233 (CCPA 1955).**

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail Fisher whose telephone number is 571-270-3502. The examiner can normally be reached on M-Th 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718 or Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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